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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/717,883	11/21/00	SALCEDA S	DEX-0115

026259
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HM12/0615

EXAMINER	
DAVIS,N	
ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/717,883	SALCEDA ET AL.	
	Examiner	Art Unit	
	Natalie A Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a diagnostic marker comprising Ovr107, classified in class 536, subclass 24.31.

II. Claims 3-7, drawn to a method of diagnosing, staging, and monitoring cancer, classified in class 435, subclass 4.

III. Claim 8, drawn to a method of identifying therapeutic agents for imaging and treating cancer classified in class 435, subclass 7.1.

IV. Claim 9, drawn to an antibody to Ovr107, classified in class 424, subclass 138.1.

V. Claims 10-11, drawn to a method of imaging cancer, classified in class 424, subclass 9.3.

VI. Claims 12-14, drawn to a method of treating cancer, classified in class 424, subclass 183.1.

VII. Claim 15, drawn to a method of inducing an immune response, classified in class 424, subclass 184.1.

VII. Claim 1, drawn to a vaccine comprising Ovr 107, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I, IV (products) and II, V-VII (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case the products of Groups I, IV may be used for a number of different processes that are very much unrelated. For example, the antibody of Group IV may not only be used in the method of Group III, but may also be used for immunopurification. The methods of Groups II, V-VII may be practiced using various therapeutic agents and do not necessarily have to be used with the products of Groups I, IV.

Materially different products, such as a polypeptide, may be used in the method of Groups II, V-VII.

3. The inventions of Groups I and IV are structurally and functionally different, are drawn to structurally and functionally different molecules.

4. Inventions II, V-VII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and require different search strategies, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Attorney Tyrrell on 29 May a provisional election was made with traverse to prosecute the invention of Group II, claims 3-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-2 and 8-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The abstract of the disclosure is objected to because it is not in compliance with Rule 37 CFR 1.72(b). The content of a patent abstract should be such as to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to ascertain quickly the

character of the subject matter covered by the technical disclosure and should include that which is new in the art to which the invention pertains. The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 250 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

9. Claims 3-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..." The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method of diagnosing the presence and metastases of cancer, in addition to the staging, and monitoring for onset of metastasis and stage changes, wherein the expression levels of Ovr107 in cells, tissues, or bodily fluids in a patient as compared to expression levels in normal human control samples.

The state of the prior art and the predictability or lack thereof in the art: The specification does not disclose whether a mutated form of the gene characterized by SEQ ID NO:1 encoding Ovr107 results in cancer, it only discloses the sequence and the fact that it is expressed in ovarian and an array of cancers. Additionally, it fails to give any biological activity for Ovr 107 and there is no art on record that discloses any specific activity for it or any correlation of its expression levels to ovarian or any other cancer. Since there is no evidence in the art teaching Ovr107 expression levels and its correlation with cancer, it would be very unpredictable to diagnose cancer based on Ovr107 expression.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order for the skilled artisan to be able to practice the invention as claimed. The specification discloses the detection of Ovr107 expression in various cancer tissue (Table 2, p.21), but does not provide guidance as to what level of Ovr107 expression would constitute abnormal levels and how these levels would be indicative of a disorder. Is any level including the over or underexpression of Ovr107 expression indicative of a disorder? In addition, is merely the detection of Ovr107 expression in known cancers definitive evidence of cancer diagnosis, it merely shows that Ovr107 is detectable in various tissues. A diagnosis is interpreted as being the determination of which two or more diseases with similar symptoms is the one from which the patient is suffering, by a systemic comparison and contrasting of the clinical findings. The specification fails to give any comparison or contrasting of clinical findings.

The breadth of the claims and the quantity of experimentation needed: Since it is not known in the art if Ovr107 levels in cells tissue, or bodily fluids may be indicative of cancer when compared to normal, it would be extremely unpredictable to use Ovr107 levels as a method of diagnosis, staging and monitoring of cancer and metastasis. Until some substantial evidence, as indicated above, can be attributed to the claimed method, one of ordinary skill in the

art would be required to perform additional experimentation in order to practice the invention as claimed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, Ph.D.
June 14, 2001

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER